ARC 7633B

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 13, "Sterile Compounding Practices," Iowa Administrative Code.

The amendments combine the requirements for testing and quarantine of sterile compounds into a single subrule, including rescinding a duplicative subrule, and clarify the products and criteria for quarantine and testing.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the December 31, 2008, Iowa Administrative Bulletin as **ARC 7446B**. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the February 17, 2009, meeting of the Board of Pharmacy.

These amendments will become effective on April 15, 2009.

These amendments are intended to implement Iowa Code sections 124.301, 155A.2, 155A.13, and 155A.13A.

The following amendments are adopted.

ITEM 1. Amend subrule 13.24(4) as follows:

13.24(4) *Testing and quarantine requirements.* All high-risk preparations, except those for inhalation and ophthalmic administration, that are prepared in groups of 25 or more identical single-dose containers or in multiple-dose vials for administration to multiple patients, or that are exposed longer than 12 hours at 2 to 8 degrees Celsius ~~and~~ or longer than 6 hours at warmer than 8 degrees Celsius before they are sterilized, shall be quarantined and tested to ensure that the preparations are sterile and that they do not contain excessive bacterial endotoxins before they are dispensed or administered.

ITEM 2. Rescind subrule **13.24(6)**.

[Filed 2/20/09, effective 4/15/09]
[Published 3/11/09]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 3/11/09.